(21) (22)

Nos. 95-754 and 95-886

Supreme Court, U.S.
FILED
MAR 18 1996
CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC., PETITIONER

v.

LORA LOHR, ET VIR.

LORA LOHR, ET VIR., PETITIONERS

v.

MEDTRONIC, INC.

ON WRITS OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS/CROSS-PETITIONERS

DREW S. DAYS, III
Solicitor General

EDWIN S. KNEEDLER
Deputy Solicitor General

STEPHEN W. PRESTON
Deputy Assistant Attorney General

RICHARD H. SEAMON
Assistant to the Solicitor General

DOUGLAS N. LETTER
MICHAEL S. RAAB
Attorneys
Department of Justice
Washington, D.C. 20530
(202) 514-2217

37 pp

QUESTION PRESENTED

Whether 21 U.S.C. 360k(a) preempts the state-law tort claims asserted by respondents/cross-petitioners concerning the allegedly defective medical device manufactured by petitioner.

TABLE OF CONTENTS

	Page
Interest of the United States	1
Statement	2
A. Statutory background	2
B. The present litigation	7
Summary of argument	9
Argument:	
Section 521 of the Federal Food, Drug, and Cosmetic Act does not require summary judgment for Medtronic on the ground that the state-law tort claims asserted by the Lohrs are preempted	11
I. Section 521 of the Act preempts only certain state substantive requirements and does not categorically preempt state tort remedies	11
II. The FDA's clearance of Medtronic's device under Section 510(k) of the Act does not preempt the Lohrs' defective-design claims	19
III. The existence of good manufacturing practices promulgated by the FDA under the Act does not require summary judgment for Medtronic on the defective-manufacture claims	22
IV. The labeling provisions of the Act and implementing regulations do not require summary judgment for Medtronic on the Lohrs' failure-to-warn claims	27
Conclusion	29

TABLE OF AUTHORITIES

Cases:

Allis-Chalmers Corp. v. Lueck, 471 U.S. 202 (1985)	22
American Airlines, Inc. v. *Wolens*, 115 S. Ct. 817 (1995)	14, 21

Cases—Continued: Page

CSX Transp., Inc. v. *Easterwood*, 113 S. Ct. 1732 (1993) 16, 22
Chevron U.S.A. Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) 9, 27
Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) 15, 16, 22, 27
Duncan v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) 8
Hillsborough County v. *Automated Medical Labs., Inc.*, 471 U.S. 707 (1985) 9, 25
Ingersoll-Rand Co. v. *McClendon*, 498 U.S. 133 (1990) 22
Kennedy v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) 16
Morales v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) 18, 22
Pilot Life Ins. Co. v. *Dedeaux*, 481 U.S. 41 (1987) .. 22
San Diego Bldg. Trades Council v. *Garmon*, 359 U.S. 236 (1959) 16
Silkwood v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984) 15
Talbott v. *C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995) 26
United States v. *Utah Constr. & Mining Co.*, 384 U.S. 394 (1966) 26

Statutes and regulations:

Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 301 *et seq.*:
21 U.S.C. 321(h) 3
21 U.S.C. 331(*l*) 27
21 U.S.C. 333(f)(2)(A) 26
21 U.S.C. 333(f)(1)(B)(i) 24
21 U.S.C. 351 (1976) 2
21 U.S.C. 351(f) 5
21 U.S.C. 351(f)(2)(B) 4
21 U.S.C. 351(h) 24
21 U.S.C. 352 (1976) 2, 3, 5, 27
21 U.S.C. 352(a) 27
21 U.S.C. 352(f) 27

Statutes and regulations—Continued: Page

21 U.S.C. 352(n) 27
21 U.S.C. 352(r) 27
21 U.S.C. 360(k) (§ 510(k)) 5, 6, 7, 9, 10, 19, 20, 22, 28
21 U.S.C. 360c(a) 3
21 U.S.C. 360c(a)(1)(A) 3
21 U.S.C. 360c(a)(1)(B) 3
21 U.S.C. 360c(a)(1)(C) 3
21 U.S.C. 360c(c)(2)(B) 24
21 U.S.C. 360c(f)(1) 5
21 U.S.C. 360d 3
21 U.S.C. 360e(d)(1)(A)(i) 4, 20
21 U.S.C. 360e(d)(2)(A) 4, 20
21 U.S.C. 360e(d)(2)(B) 20
21 U.S.C. 360e 27
21 U.S.C. 360e(b) 4
21 U.S.C. 360e(c) 4
21 U.S.C. 360e(d) 4
21 U.S.C. 360e(i) 19
21 U.S.C. 360h 5
21 U.S.C. 360j(e) 27
21 U.S.C. 360j(f) 3, 24
21 U.S.C. 360j(f)(2)(C) 24
21 U.S.C. 360j(g) 4, 27
21 U.S.C. 360k (§ 521) 5, 11, 14, 15, 16, 17, 18
21 U.S.C. 360k(a) (§ 521(a)) ..... *passim*
21 U.S.C. 360k(a)(1) 20, 22, 23, 24, 28
21 U.S.C. 360k(a)(2) 20
21 U.S.C. 360k(b) (§ 521(b)) 2, 6, 13, 18, 19
21 U.S.C. 371(a) 2
21 U.S.C. 374 26
21 U.S.C. 393 2
Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 21 U.S.C. 360c *et seq.* 2
§ 2, 90 Stat. 574 (21 U.S.C. 360k) 1
§ 3, 90 Stat. 575 3
Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 *et seq.* 3, 7

Statutes and regulations—Continued: Page

§ 4(b), 104 Stat. 4515-4517 (21 U.S.C. 360e (i)) 7
§ 5, 104 Stat. 4517-4518 3
§ 12(a), 104 Stat. 4523 (21 U.S.C. 360c(i)(3)(A) 7
28 U.S.C. 1441(b) 8
21 C.F.R.:
Pt. 5:
Section 5.10(a)(1) 2
Pt. 801 ..... 3, 27
Section 801.5 27
Pt. 807:
Section 807.100 19
Section 807.81 21
Section 807.87 5
Section 807.97 20
Pt. 808:
Section 808.1(b) 15
Section 808.1(d) 8
Section 808.1(d)(2) 13
Section 808.1(d)(6) 13
Section 808.20(c)(1) 18
Pt. 812 4
Pt. 814 4
Section 814.44(d) 4
Section 814.45(c) 4
Pt. 820 3
Section 820.20 24
Section 820.25 24
Pt. 821:
Section 821.50 26
Pt. 860:
Section 860.3(c)(1) 3
Pt. 870:
Section 870.3680(b) 7

Regulations—Continued: Page

Pt. 880:
Section 880.6230 3
Pt. 884:
Section 884.5460 3
Section 884.5470 3

Miscellaneous:

Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511 (1988) 4
121 Cong. Rec. (1975):
p. 10,688 15
p. 10,689 15
p. 10,693 6
122 Cong. Rec. (1976):
p. 5850 15
p. 13,779 2
42 Fed. Reg. (1977):
p. 9186 13
p. 9293 25
p. 30,383 12
pp. 30,383-30,384 25
p. 30,384 12
p. 30,387 12
45 Fed. Reg. 67,329 (1980) 25
59 Fed. Reg. 23,731 (1994) 7
H.R. Rep. No. 808, 101st Cong., 2d Sess. (1990) 4, 6, 19
H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) 2, 14, 15
Joint Hearings on FDA Practice and Procedure Before the Subcomm. on Health of the Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 94th Cong., 1st Sess. (1975) 16

Miscellaneous—Continued: Page

Jonathan S. Kahan, *Premarket Approval versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510 (1984) 5

David A. Kessler, et al., *The Federal Regulation of Medical Devices*, 317 New Eng. J. Med. 357 (1987) 4

S. Rep. No. 33, 94th Cong., 1st Sess. (1975) 2, 15

S. Rep. No. 513, 101st Cong., 2d Sess. (1990) 6

Subcommittee on Oversight and Investigations of the House Comm. on Energy and Commerce, 98th Cong., 1st Sess., *Medical Device Regulation: The FDA's Neglected Child* (Comm. Print 98-F 1983) 6

Webster's Third New International Dictionary (1986) 14

In the Supreme Court of the United States

OCTOBER TERM, 1995

No. 95-754

MEDTRONIC, INC., PETITIONER

v.

LORA LOHR, ET VIR.

No. 95-886

LORA LOHR, ET VIR., PETITIONERS

v.

MEDTRONIC, INC.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS/CROSS-PETITIONERS

INTEREST OF THE UNITED STATES

This case concerns the interpretation of Section 521(a) of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 360k(a), a provision added to the Act by the Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 574, to govern the preemption of state and local requirements with respect to medical devices.

The Secretary of Health and Human Services is responsible for administering the Act through the Food and Drug Administration (FDA). 21 U.S.C. 371(a), 393; 21 C.F.R. 5.10(a)(1). The FDA has promulgated regulations that interpret Section 521(a) and implement the substantive provisions of the Medical Device Amendments, and the FDA is authorized to grant exemptions from preemption under Section 521(b) of the Act. Moreover, the FDA's administration of the Act is affected by the extent to which state-law remedies for defective medical devices are available.

STATEMENT

A. Statutory Background.

1. Before 1976, the federal government had quite limited authority over medical devices. See Pet. App. 2a.[1] It consisted primarily in the FDA's authority to take action against adulterated or misbranded devices. See 21 U.S.C. 351, 352 (1976); see also H.R. Rep. No. 853, 94th Cong., 2d Sess. 6 (1976). In 1976, in response to injuries caused by the Dalkon Shield intrauterine device and other medical devices, Congress expanded federal authority over medical devices by enacting the Medical Device Amendments, Pub. L. No. 94-295, 90 Stat. 539 (codified primarily at 21 U.S.C. 360c *et seq.*). See S. Rep. No. 33, 94th Cong., 1st Sess. 1 (1975); H.R. Rep. No. 853, *supra*, at 8; 122 Cong. Rec. 13,779 (1976) (remarks of Rep. Fountain). The Amendments were "intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, *supra*, at 12.

[1] References to "Pet. App." are to the Appendix to the Petition in No. 95-754.

The Amendments required the FDA to classify every medical device in commercial distribution at the time of enactment into one of three categories, depending on the degree of regulation necessary to ensure its safety and effectiveness. See 21 U.S.C. 360c(a).[2] Class I devices, such as tongue depressors, are subject to "general controls." 21 U.S.C. 360c(a)(1)(A); 21 C.F.R. 860.3(c)(1), 21 C.F.R. 880.6230; Pet. App. 4a. General controls relate to, among other matters, the labeling of devices and "good manufacturing practices" (GMPs). 21 U.S.C. 360c(a)(1)(A); see 21 U.S.C. 352, 360j(f), 21 C.F.R. Pts. 801, 820. Class II devices, such as tampons, are subject to both general controls and "special controls." 21 U.S.C. 360c(a)(1)(B); 21 C.F.R. 884.5460, 884.5470. Special controls may include performance standards, which are criteria specifically formulated for a particular type of device. *Ibid.*; 21 U.S.C. 360d.[3]

Class III devices—which include pacemaker leads, the device at issue here—present the greatest potential risk to human health.[4] Consequently, Class III devices are in

[2] The Amendments also revised the statutory definition of "device," but not in ways relevant here. 90 Stat. 575. In general, the term includes, *inter alia*, any item that is intended to affect the structure of any function of the body and that does not rely on chemical action to achieve its intended effect. See 21 U.S.C. 321(h).

[3] The Amendments provided for the development of performance standards for Class II devices. In the Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, 104 Stat. 4511, Congress expanded the range of controls applicable to Class II devices; these "special controls" for Class II devices include, but are no longer limited to, performance standards. SMDA § 5, 104 Stat. 4517-4518; 21 U.S.C. 360c(a)(1)(B).

[4] 21 U.S.C. 360c(a)(1)(C) defines a Class III device as one the safety and effectiveness of which cannot reasonably be assured through general and special controls and that either is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury."

general subject not only to general controls and special controls but also to premarket approval, which the FDA grants if there is reasonable assurance that the specific device that a particular manufacturer seeks to market is safe and effective. 21 U.S.C. 360e(d)(1)(A)(i) and (2)(A); see 21 C.F.R. 814.44(d), 814.45(c).[5] Premarket-approval (PMA) applications must be supported by detailed test data on safety and effectiveness, and the PMA process is extensive for both the device-manufacturer and the FDA. See 21 U.S.C. 360e(c) and (d); 21 C.F.R. Pt. 814.

The Amendments did not require that Class III devices on the market at the time of enactment be withdrawn from the market pending premarket approval. Instead, the Amendments provided that such a device would not be subject to premarket approval until 90 days after the FDA had finally classified it as a Class III device *and* had promulgated a regulation requiring premarket approval for that device. 21 U.S.C. 360e(b), 351(f)(2)(B); see also H.R. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990).

The Amendments also were designed to ensure that the provisions just described did not give manufacturers of pre-Amendments Class III devices a competitive advantage over manufacturers who sought to market similar devices *after* the Amendments were enacted.[6] Thus, a post-Amendment device satisfying the criteria for Class III classification may be marketed without premarket approval if the FDA determines that it is "substantially equivalent" to a pre-Amendments Class III device, and

[5] Class III devices may, however, be approved for investigational use without premarket approval, under an "investigational device exemption[]." 21 U.S.C. 360j(g); see 21 C.F.R. Pt. 812.

[6] See David A. Kessler, et al., *The Federal Regulation of Medical Devices*, 317 New Eng. J. Med. 357, 359 (1987); Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 513 (1988).

thereafter it need not receive premarket approval until premarket approval is required for the pre-Amendments device to which it is substantially equivalent. See 21 U.S.C. 360(k), 360c(f)(1).

The process by which the FDA clears "substantially equivalent" devices for marketing is known either as the "510(k) process" (a name derived from Section 510(k) of the Act, 21 U.S.C. 360(k), upon which the process is based) or as the "premarket notification" process (because Section 510(k) allows such devices, after issuance of an FDA order, to be marketed 90 days after the manufacturer notifies the FDA of its intention to do so). The 510(k) process traditionally has been much less extensive than the PMA process, particularly prior to 1990. See pages 6-7, *infra*; 21 C.F.R. 807.87.[7] It accordingly does not impose a significant competitive disadvantage on the manufacturers of post-Amendments devices relative to the manufacturers of the pre-Amendments Class III devices that are substantially equivalent.

The Amendments did not expressly authorize private actions, but they did give certain remedial powers to the Secretary. See 21 U.S.C. 360h. The Amendments also preserved the Secretary's power to take enforcement action against misbranded or adulterated devices. 21 U.S.C. 351(f), 352.

Finally, the Amendments included the following pre-emption provision, in Section 521(a) of the Act:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

[7] See generally Jonathan S. Kahan, *Premarket Approval versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510 (1984).

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a). Subsection (b) of Section 521 authorizes the Secretary to exempt a state or local requirement from preemption under specified circumstances. 21 U.S.C. 360k(b).

2. "The FDA faced an enormous task in essentially starting from scratch in regulating devices." S. Rep. No. 513, 101st Cong., 2d Sess. 14 (1990).[8] As of 1990, the FDA had promulgated relatively few regulations requiring premarket approval for pre-Amendments Class III devices. See *id.* at 15. In addition, an unexpectedly large proportion (approximately 80%) of Class III devices marketed after 1976 was found "substantially equivalent" to pre-Amendments devices, and therefore did not require premarket approval until such approval was required for the substantially equivalent pre-Amendments Class III devices. H.R. Rep. No. 808, *supra*, 14. As a result, the 510(k) process came to serve a more significant function than simply removing a competitive disadvantage for the manufacturers of certain post-Amendments devices on a temporary basis, until the contemplated PMA regulations were in place. Instead, the vast majority of pre-Amendments Class III devices and substantially equivalent post-Amendments devices, including the device at issue here, were "effectively grandfathered from the regulation appropriate to their classification." S. Rep. No. 513, *supra*, at 15; see also Subcommittee on Oversight and Investigations of the House Comm. on Energy and Commerce, 98th Cong., 1st Sess., *Medical Device Regulation: The FDA's Neglected Child* 13-14, 18-21 (Comm. Print 98-F 1983).

---

[8] There were estimated to be 1500 companies producing 12,000 types of medical devices at the time of enactment. 121 Cong. Rec. 10,693 (1975) (remarks of Sen. Ribicoff).

3. In light of the experience under the 1976 Amendments, Congress enacted the Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, 104 Stat. 4511. The SMDA, among other things, required 510(k) submissions to include a summary of information on the safety and effectiveness of the device. See SMDA § 12 (a), 104 Stat. 4523 (21 U.S.C. 360c(i)(3)(A)). The SMDA also required the FDA, by December 1, 1995, to publish, for each pre-Amendments Class III device, a regulation that either reclassified the device or retained it in Class III. SMDA § 4(b), 104 Stat. 4515-4517 (21 U.S.C. 360e(ii)). That process is still underway. See 59 Fed. Reg. 23,731 (1994).

B. The Present Litigation.

1. The device at issue here is a pacemaker lead, a Class III device that conducts electrical impulses from a pulse generator to the heart. Pet. App. 6a; see 21 C.F.R. 870.3680(b). Medtronic received FDA clearance under Section 510(k) to market its Model 4011 pacemaker lead as a "substantially equivalent" device in 1982. As such, the Model 4011 is subject to the general controls applicable to all medical devices, but it was not required to receive premarket approval before entering the market.

2. A Model 4011 was implanted in Ms. Lohr in 1987. In 1990, it suddenly failed, requiring her to have emergency surgery. Pet. App. 6a. In 1993, Ms. Lohr and her husband filed this action for damages against Medtronic in Florida state court. Relying on Florida law, they sought to recover on the theories that the device was negligently designed and manufactured; that Medtronic breached a duty to warn the Lohrs of the Model 4011's tendency to fail suddenly; and that, because the device was defective and unreasonably dangerous to foreseeable users "[a]t the time of the design, manufacture, sale and

implantation," Medtronic was strictly liable for the defect. C.A. R.E. 8-9.[9]

Medtronic removed the suit to the federal court on diversity grounds. See 28 U.S.C. 1441(b). Medtronic later moved for summary judgment, arguing that all of the Lohrs' claims are preempted by Section 521(a) of the Act. The district court granted the motion. Pet. App. 1b-3b.

3. The court of appeals affirmed in part and reversed in part. Pet. App. 1a-36a. It held that Section 521(a) preempts the negligent-manufacture claim, the failure-to-warn claim, and the strict-liability claim to the extent it is based on defective manufacturing or labeling. *Id.* at 29a-36a. But the court held that Section 521(a) does not preempt the negligent-design claim or the strict-liability claim to the extent that it is based on defective design. *Id.* at 24a-29a.

As an initial matter, the court of appeals held that state common law applied in tort actions may constitute a "requirement" within the meaning of Section 521(a), and therefore may be subject to preemption. Pet. App. 11a-14a. The court regarded that holding to be compelled by its prior decision in *Duncan* v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994). Pet. App. 11a.

Next, the court of appeals considered the meaning of the term "requirement" as that term is used in Section 521(a) to refer to the federal provisions that have preemptive force. The court found that term ambiguous and accordingly turned to the FDA's regulation on the subject, which provides in relevant part (21 C.F.R. 808.1 (d)):

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act.

[9] The Lohrs also claimed a breach of the implied warranty of fitness and merchantability imposed by state law, but that claim was dismissed and is not at issue in this Court. See Pet. App. 6a n.3.

The court determined that the regulation reflects a reasonable interpretation of Section 521(a) and is therefore entitled to deference. Pet. App. 17a (citing *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984)); see also Pet. App. 15a (citing *Hillsborough County* v. *Automated Medical Labs., Inc.*, 471 U.S. 707, 712-714 (1985)).

The court of appeals understood the FDA's regulation to mean that "preemption-triggering requirements should, in some way, be 'restricted by nature' to a particular process, procedure, or device." Pet. App. 21a-22a (footnote omitted). Based on that understanding, the court held that the defective-manufacture claims are preempted by the good manufacturing practices (GMPs) promulgated by the FDA under the Medical Device Amendments, and that the failure-to-warn claims are preempted by the labeling provisions of the Amendments and implementing regulations. *Id.* at 31a, 33a.

The court of appeals held that Section 521(a) does not preempt the defective-design claims because the Amendments do not require any particular design for the Model 4011. Pet. App. 25a-29a. The court rejected Medtronic's argument that the FDA's clearance of the device under Section 510(k) constitutes a "requirement" that preempts tort claims implicating the device's safety or effectiveness. Pet. App. 27a. The court determined that 510(k) clearance does not reflect "a finding of safety and effectiveness." *Ibid.*

SUMMARY OF ARGUMENT

I. Section 521(a) of the Act does not categorically preempt state tort remedies. Section 521(a) preempts certain state "requirement[s]." The FDA has consistently, and reasonably, construed the term "requirement" to refer

to substantive, but not remedial, provisions. Applying that approach here, a substantive obligation created by state tort law, such as the duty to use due care, may constitute a "requirement" within the meaning of Section 521(a); but that term does not encompass a state tort principle entitling a plaintiff to recover damages for the defendant's breach of a substantive common-law obligation.

II. The court of appeals correctly held that the FDA's clearance of petitioner's device under Section 510(k) of the Act does not preempt the defective-design claims. The clearance of a post-Amendments Class III device under Section 510(k) reflects a determination that the device is "substantially equivalent" to a pre-Amendments device and therefore may be legally marketed, rather than an independent determination that the device is safely designed. Since the FDA will not have determined the safety and effectiveness of the pre-Amendments device, the "substantial equivalence" determination is not tantamount to a determination of safety and effectiveness, much less a determination that a particular design is required by the Act.

III. The court of appeals erred in holding that the "good manufacturing practices" (GMPs) promulgated by the FDA preempt the defective-manufacture claims. The court of appeals reasoned that, because the GMPs address "almost every aspect of the manufacturing process," a jury's determination that some aspect of the manufacture of petitioner's device was inadequate "could" impose a requirement that was different from, or in addition to, the requirements imposed by the GMPs. But Section 521(a) conditions preemption on a determination that the particular state requirement on which the plaintiff relies "*is* different from, or in addition to," a federal requirement. The mere possibility that state law might diverge in some respects is insufficient. The court of appeals did not specifically identify any GMP requirement from which a jury determination in this case would necessarily depart.

IV. The court of appeals also erred in holding that the labeling provisions of the Act and implementing regulations preempt the failure-to-warn claims. As an initial matter, while the Act and its regulations address the labeling of devices, they generally do not prescribe requirements for advertising or other modes of communication. Thus, the failure-to-warn claims are not preempted insofar as they concern modes of communication other than labeling. Nor are they preempted insofar as they concern labeling. The Act and regulations for the most part address the labeling of devices only in generalized terms. A jury's determination that a particular device was inadequately labeled would not necessarily be based on any common-law requirement "different from, or in addition to," those general labeling provisions under federal law.

ARGUMENT

SECTION 521 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DOES NOT REQUIRE SUMMARY JUDGMENT FOR MEDTRONIC ON THE GROUND THAT THE STATE-LAW TORT CLAIMS ASSERTED BY THE LOHRS ARE PREEMPTED

I. Section 521 Of The Act Preempts Only Certain State Substantive Requirements And Does Not Categorically Preempt State Tort Remedies

Section 521 of the Food, Drug and Cosmetic Act (FDCA or Act) does not categorically preempt state tort remedies, or any other form of state-created remedies, as applied to persons who manufacture and sell defective medical devices. Section 521 preempts certain state "requirement[s]" regarding such devices. 21 U.S.C. 360k(a). The FDA has consistently interpreted that term to refer to substantive, rather than remedial, state provisions. A substantive common-law obligation, such as the duty

to use due care, may constitute a "requirement" under Section 521(a), just as a substantive statutory obligation may do so. But the term "requirement" does not encompass the judicially created principle that allows a plaintiff to recover damages for the defendant's violation of a substantive common-law obligation.

A. The FDA's view that Section 521(a) does not preempt state remedies, as such, is clear from regulations and advisory rulings providing that a State may use state-created remedies to enforce state substantive requirements for medical devices, if those substantive requirements are substantially identical to federal substantive standards. In that situation, preemption does not occur under Section 521(a) because the state substantive "requirement[s]" are not "different from, or in addition to," federal requirements applicable under the FDCA.

The FDA took that view in June 1977, when it proposed regulations interpreting Section 521(a). 42 Fed. Reg. 30,383. In the preamble to the proposed regulations, the FDA stated (*id.* at 30,384):

> Section 521(a), by its terms, applies only to those State or local requirements that are "different from, or in addition to" FDA requirements. Accordingly, * * * the Commissioner concluded that the provision does not preempt those State or local requirements that are equal to or substantially identical to FDA requirements.

The FDA further stated in the preamble that Section 521(a) does not preempt "general State or local law provisions governing the enforcement of requirements applicable to medical devices," because "[s]uch general enforcement provisions are not themselves requirements." *Ibid.* The proposed regulations incorporated that position. See *id.* at 30,387.[10] The relevant regulatory provisions

[10] The FDA had previously taken the same view in February 1977, when it published a proposed ruling on California's application to have certain state statutory provisions applicable to medical devices exempted from preemption under Section 521(b). 42 Fed. Reg. 9186 (1977).

were adopted as final regulations and remain unchanged in relevant part. 21 C.F.R. 808.1(d)(2) and (6).

The FDA has made clear that the state "enforcement provisions" that it considers not to constitute "requirement[s]" include *judicial* remedies sought by private parties to enforce state substantive requirements. In an advisory opinion issued in 1984, the FDA stated that Section 521(a) "does not preempt the application of State law injunctive remedies" to pre-Amendments intrauterine contraceptive devices, because "[r]ules or requirements established by States to govern the legal remedies available under the State judicial system are not 'requirements with respect to a device' within the meaning of section 521(a) of the act." Resp./Cross-Pet. Br. App. 13a. Although the advisory opinion dealt with injunctive remedies, its conclusion fully applies to damage remedies in a tort action. Moreover, tort remedies are reasonably characterized as "enforcement provisions" within the meaning of the FDA's regulation interpreting Section 521(a), because they enable a plaintiff to enforce a substantive duty imposed upon the defendant by the State's common law.

B. The FDA's interpretation of Section 521(a) not to preempt state tort remedies accords with the text of Section 521(a), as well as its legislative history and purpose. Section 521(a) provides that no State "may establish or continue in effect with respect to a device * * * any requirement" that (1) "is different from, or in addition to," any requirement applicable under the FDCA, and (2) relates to the safety and effectiveness of the device or other matters included in a requirement applicable to the device under the FDCA. 21 U.S.C. 360k(a). The term "requirement" in that context is most naturally read

to refer to the attributes of a device itself or to substantive duties imposed on persons who manufacture or sell it, rather than to remedial provisions. See *Webster's Third New International Dictionary* 1929 (1986) ("requirement," def. b: "something called for or demanded: a requisite or essential condition"). That interpretation is consistent with the well-established distinction between rights or duties, on the one hand, and remedies or other means for enforcing rights or duties, on the other hand. Cf. *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817, 824 (1995) (distinguishing, for preemption purposes, between state-law action based on violation of "state-imposed obligations," and state-law action to remedy violation of "privately ordered obligations").

Moreover, the legislative history of the 1976 Amendments indicates that Congress intended Section 521 to protect the manufacturers of medical devices from conflicting substantive requirements. See H.R. Rep. No. 853, *supra*, at 45 (preemption provision covers statutes providing for inconsistent "regulation" of devices). By contrast, nothing in the legislative history suggests that Congress also intended to shield manufacturers from state-created remedies for violations of state substantive requirements that were not "different from, or in addition to," federal substantive requirements. The legislative history also reflects Congress's recognition that, even after the Amendments were fully implemented, "no regulatory mechanism can guarantee that a product will never cause injury." H.R. Rep. No. 853, *supra*, at 16. Yet the legislative history contains no evidence that Congress intended to eliminate state tort remedies even for those injuries that are attributable to *defective* devices, especially ones marketed *before* the Amendments were fully implemented through the promulgation of regulations mandating premarket approval for those devices. That silence is significant in light of Congress's specific awareness of the numerous personal injuries caused by the

Dalkon Shield.[11] Cf. *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Against this background, FDA has reasonably interpreted the term "requirement" in Section 521(a) not to preempt state tort remedies or other state remedial provisions. Analysis under Section 521 should therefore focus on the state substantive provisions invoked by the Lohrs to support an award of damages and the federal substantive provisions invoked by Medtronic to defeat such an award.

C. The distinction between substantive and remedial provisions is not the same as the distinction between substantive obligations imposed by common law and substantive obligations imposed by positive enactments, such as statutes and regulations. The Lohrs rely on the latter distinction to argue that the term "requirement" in Section 521(a) does not preempt any state tort claims concerning defective medical devices. Resp./Cross-Pet. Br. 16-34. That argument, in our view, is difficult to square with *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 527-529 (1992).[12]

---

[11] S. Rep. No. 33, *supra*, at 1; H.R. Rep. No. 853, *supra*, at 8; 121 Cong. Rec. 10,688 (1975) (remarks of Sen. Kennedy); *id.* at 10,689 (remarks of Sen. Nelson); 122 Cong. Rec. 5850 (1976) (remarks of Rep. Abzug); see also *Joint Hearings on FDA Practice and Procedure Before the Subcomm. on Health of the Comm. on Labor and Public Welfare and the Subcomm. on Admin. Practice and Procedure of the Senate Comm. on the Judiciary*, 94th Cong., 1st Sess. 47 (1975).

[12] The FDA has not heretofore taken a formal position specifically on whether the term "requirement" in Section 521(a) encompasses obligations established by a State's common law of torts. However, the FDA regulations interpreting Section 521(a) do describe it as preventing States from establishing or continuing in effect "any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*)." 21 C.F.R. 808.1(b) (emphasis added)). It has been suggested that the term "court decision" could be read to refer to a decision construing

In *Cipollone*, this Court held that a failure-to-warn claim against a cigarette company was preempted by a federal provision that stated: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 505 U.S. at 515 (quoting statute). The Court rejected the plaintiff's argument that "common-law damages actions do not impose 'requirement[s] or prohibition[s].'" *Id.* at 521. The plurality concluded that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law," *ibid.*; see generally *id.* at 521-523, and the separate opinion of Justice Scalia, joined by Justice Thomas, specifically agreed with that conclusion, *id.* at 548-549. See also *CSX Transp., Inc.* v. *Easterwood*, 113 S. Ct. 1732, 1737-1738 (1993); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959).

The Lohrs contend that *Cipollone* is distinguishable. Resp./Cross-Pet. Br. 18-19, 24-25. They rely on three features of the text of Section 521. In our view, none of those features suffices to distinguish *Cipollone*.

First, subsection (a) of Section 521 uses the term "requirement" to refer to both the state provisions that are subject to preemption and the federal provisions that have preemptive force. The Lohrs point out that the federal "requirement[s]" are imposed solely by positive enact-

a statute, regulation, or ordinance, and not to a decision applying the common law. See *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453, 1461-1462 (9th Cir. 1995) (Reinhardt, J., concurring); Resp./Cross-Pet. Br. 26 n.7. We are not aware of any contemporaneous agency materials that so confines the regulation's reference to "any requirement having the force and effect of law * * * established by * * * court decision." The Lohrs cite a 1987 letter from an FDA official in support of their position (see Resp./Cross-Pet. Br. 23 n.5, App. 14a), but that letter was not a formal advisory opinion, its import is unclear, and it contains no legal reasoning.

ments: the FDCA and implementing regulations. They reason that the state "requirement[s]" should also be limited to positive enactments, and therefore exclude standards developed and applied at common law. Resp./Cross-Pet. Br. 18-19.

The problem with that reasoning is that the limitation on the type of federal provisions that have preemptive force is not attributable to the term "requirement." It is, instead, attributable to the words that modify "requirement." A state provision may be preempted only by a federal requirement "applicable under this chapter." 21 U.S.C. 360k(a). It is the latter phrase that limits the federal provisions having preemptive force to those imposed by the FDCA and implementing regulations, rather than by common law.

Second, Section 521(a) bars a State from "establish-[ing] or continu[ing] in effect *with respect to a device*" certain state requirements. 21 U.S.C. 360k (emphasis added). The Lohrs argue that the "with respect to" phrase limits the scope of the provision to state requirements that specifically refer or relate to medical devices, and therefore excludes general common-law duties. Resp./Cross-Pet. Br. 19-21.

That argument is strained as a grammatical matter. Section 521(a) provides in relevant part that no State "may establish or continue in effect *with respect to a device intended for human use* any requirement * * * which is different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. 360k(a) (emphasis added). The Lohrs read the italicized phrase as modifying "requirement"; thus, they assert a "contrast between positive-law requirements 'with respect to a device' and general common-law duties." Resp./Cross-Pet. Br. 20. But the "with respect to" phrase cannot modify the word "requirement," because "requirement" comes *after* that phrase. Rather, the phrase modifies the words ("establish or continue to effect") that

come immediately *before* it. The phrase indicates that, if a state requirement meets the conditions for preemption, the State cannot establish or continue that requirement in effect "with respect to a device." The phrase thus preserves the authority of a State to have the requirement in effect insofar as it applies to things *other* than medical devices. By allowing in this manner for partial preemption of state "requirement[s]," the "with respect to" clause suggests that such a "requirement" may be one of general applicability. Cf. *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992).

Third, subsection (b) of Section 521 allows the FDA to exempt state "requirement[s]" from preemption under subsection (a). The Lohrs assert that it would be difficult for a State to seek an exemption for a common-law "requirement" developed or applied in judicial decisions. Resp./Cross-Pet. Br. 24. Based on that assertion, they argue that subsection (b) contemplates that the state "requirement[s]" for which an exemption will be sought are ones imposed by positive enactments, such as state statutes and administrative regulations, and that the "requirement[s]" that would otherwise be subject to preemption under subsection (a) should be limited in the same manner.

Although it may be difficult, as a practical matter, for a State to request an exemption for a common-law "requirement," such a request is not legally barred on the face of subsection (b).[13] Moreover, respondents/cross-petitioners assume that Congress intended to ensure the availability of an exemption under subsection (b) for

[13] The FDA's regulations do not expressly contemplate exemptions for State "requirement[s]" imposed in judicial decisions applying common-law principles. See 21 C.F.R. 808.20(c)(1) (State or locality must identify and provide current copy of the "statute, rule, regulation, or ordinance" for which it seeks an exemption). The FDA has not, however, taken the position that Section 521(b) renders such exemptions unavailable, and the FDA does not do so here.

every type of "requirement" that is subject to preemption under subsection (a). That assumption is not compelled by the text of the statute. Subsection (b) states that the Secretary "may" grant an exemption; it does not say that she "must" do so. Moreover, Congress might well have contemplated that the Secretary would decide, in her discretion, to grant exemptions chiefly for statutory and administrative "requirement[s]," rather than for "requirement[s]" developed in the course of case-by-case adjudication at common law, because judicial decisions are more numerous and their meaning and precedential effect are sometimes unclear.

II. The FDA's Clearance Of Medtronic's Device Under Section 510(k) Of The Act Does Not Preempt The Lohrs' Defective-Design Claims

The court of appeals correctly held that Section 521(a) does not preempt the Lohrs' claims regarding the design of the Model 4011. Pet. App. 24a-29a (negligence claim concerning design), 35a (strict liability claim concerning design). Medtronic bases its argument to the contrary on the fact that the FDA cleared the Model 4011 under Section 510(k) of the Act, 21 U.S.C. 360(k), as a substantially equivalent device. That argument reflects a misunderstanding of the 510(k) process.

The clearance of a post-Amendments device under Section 510(k)—based on a determination that the device is substantially equivalent to a pre-Amendments Class III device—does not reflect a determination by the FDA that the device is safe and effective, much less a specific determination that the device's design is required to ensure its safety and effectiveness. "[A] determination of substantial equivalence * * * is not equivalent to an approval by the FDA of the device's safety and effectiveness." H.R. Rep. No. 808, *supra*, at 14; see 21 U.S.C. 360e(i); 21 C.F.R. 807.100. As the court of appeals observed, the FDA ordinarily will not have determined whether the

pre-Amendments device was safe and effective (since the FDA lacked the general authority to do so prior to enactment of the Amendments). Pet. App. 26a. Accordingly, FDA regulations specify that a substantial equivalence determination "does not in any way denote official approval of the device," and that any representation conveying "an impression of official approval * * * is misleading and constitutes misbranding." 21 C.F.R. 807.97.

A "substantial equivalence" determination differs in this respect from premarket approval, which is required for other post-Amendments devices that are classified in Class III. As explained above, the FDA may not approve a PMA application without "a showing of reasonable assurance" that the device is "safe" and "effective" for "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. 360e(d)(1)(A)(i) and (2)(A)-(B).[14]

There is an additional reason why the defective-design claims would not be preempted by a substantial equivalence determination, even if it were deemed tantamount to the determination of safety and effectiveness required for premarket approval. Neither the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of a device originates with its manufacturer. Even if design specifications could be characterized as "requirement[s]" in some sense, once the FDA clears the device under Section 510(k), they are not "requirement[s] *applicable* to the device *under th*[*e Act*]." 21 U.S.C. 360k(a)(2) (emphasis added); see also 21 U.S.C. 360k(a)(1). Instead, the specifications are applicable to the device as a result of the voluntary decision of a private party, the manufacturer, to introduce the device into the market with a design of the manufacturer's choosing.

[14] There is no occasion in this case to consider the extent to which the PMA process may result in requirements applicable to a device under the FDCA that would trigger preemption under Section 521(a).

That federal law attaches a consequence to such private decisions does not convert them into federal "requirements." Cf. *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. at 824.

Medtronic argues (Pet. Br. 44-45) that the defective-design claims are preempted because the manufacturer of a "substantially equivalent" device must obtain FDA clearance before it can change the design of the device. FDA clearance is also required, however, when the manufacturer of a pre-Amendments Class III device seeks to change its design. 21 C.F.R. 807.81. In the absence of a design change (or the promulgation of a PMA regulation for the device), the marketing of such a device will never have been cleared (much less approved) by the FDA. In light of that fact, no one could plausibly argue that defective-design claims regarding pre-Amendments Class III devices are preempted.[15] Congress enacted the Medical Device Amendments to increase protection against defective devices. If Section 521(a) preempted claims regarding devices that were not even subject to regulation under the Amendments, the Amendments would have *decreased* the level of protection. Thus, a defective-design claim concerning a device (whether pre- or post-Amendments) is not preempted merely because the FDA must clear certain changes in the device's design.

[15] Although Medtronic does not advance that argument in this Court, it did advance the argument below, and the court of appeals correctly rejected it. Pet. App. 27a-29a. As the court reasoned, construing Section 521(a) to bar tort claims against manufacturers of pre-Amendments devices would accord a benefit "to devices that never paid the [Amendments'] regulatory 'price' for market entry." Pet. App. 28a. At the same time, the court recognized that allowing such claims "would not disturb a manufacturer's developmental calculus because presumably, when such devices were first introduced, the devices were considered a wise business investment despite state-imposed tort liability." *Ibid.* The result of preemption therefore would be to give the manufacturers of pre-Amendments devices "a regulatory windfall." *Ibid.*

III. The Existence Of Good Manufacturing Practices Promulgated By The FDA Under The Act Does Not Require Summary Judgment For Medtronic On The Lohrs' Defective-Manufacture Claims

The court of appeals erred in holding that the Lohrs' defective-manufacture claims necessarily are preempted by Section 521(a) of the Act. Pet. App. 29a-31a (negligence claim regarding manufacture), 35a (strict liability claim regarding manufacture). The court determined that the common law on which those claims are based "constitutes * * * state requirement[s] 'different from, or in addition to' the GMP regulations' specific manufacturing requirements." *Id.* at 31a; see also *id.* at 35a. That determination rests on an inadequate analysis of the "different from, or in addition to" condition for preemption under Section 521(a). 21 U.S.C. 360k(a)(1).[16]

By virtue of the "different from, or in addition to," limitation, it is necessary to compare the state requirement that is assertedly preempted to the federal requirement that assertedly preempts it. When the state requirement is asserted to be general state common-law principles applied in tort actions, the court must focus on the specific claim, rather than general principles.[17] Similarly,

[16] The court of appeals based its preemption holding regarding the defective-manufacture claims solely on the GMPs. The court rejected Medtronic's argument that those claims are barred as a result of the FDA's 510(k) clearance of the Model 4011. Pet. App. 30a. The court's rejection of the 510(k) argument was correct for reasons discussed in Section II, *supra*, pp. 19-21. In any event, FDA clearance of a model under Section 510(k) does not signify a determination by the FDA that the particular device purchased by the plaintiff was properly manufactured.

[17] See *CSX Transp.*, 113 S. Ct. at 1738, 1742-1743; *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 45-48 (1987); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 209 (1985); see also *Morales*, 504 U.S. at 386; *Cipollone*, 505 U.S. at 553-554 (Scalia, J., concurring in part and dissenting in part); cf. *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 138-142 (1990).

the court must identify the particular federal requirement that, the defendant contends, has preemptive force. Only then can the court decide whether the imposition of liability based on the plaintiff's claim would be based on a requirement that is actually "different from, or in addition to," a federal requirement.[18]

The court of appeals failed to undertake that analysis with the necessary precision. The court reasoned that the defective-manufacture claims invited a jury to decide how the Model 4011 should have been built, and that the jury's decision "*could* create a standard of conduct 'different from, or in addition to' " the GMPs. Pet. App. 30a (emphasis added). The court did not, however, identify any GMP from which a jury verdict in favor of the Lohrs would necessarily depart. It merely observed that "the GMP regulations create standards for almost every aspect of the manufacturing process." *Id.* at 31a. At the same time, the court recognized that those regulations "are written in necessarily broad language." *Ibid.* Thus, the court based its preemption holding on the mere possibility that a tort plaintiff's defective-manufacture claim might, if successful, effectively be based on a requirement that a device manufacturer do something "different from, or in addition to," something required by the general standards enunciated in the GMPs. Under Section 521(a), however, a state requirement is preempted only if it "*is* different from, or in addition to," a federal requirement. 21 U.S.C. 360k(a)(1) (emphasis added). The Lohrs have not alleged violations of state common-law standards governing defective manufacture that are different from, or in addition to, the applicable GMPs or any other federal requirements. The court of appeals therefore erred in affirming summary judgment for Medtronic on the defective-manufacture claims.

[18] The Secretary, in her discretion, may specify in a regulation or an order approving the marketing of a device what requirements are and are not applicable to the device under the FDCA.

Beyond identifying the error in the court of appeals' analysis, this Court need not essay a comprehensive delineation of the circumstances in which defective-manufacture claims may be preempted by the GMPs. We believe, however, that, for the most part, the GMPs, standing alone, are formulated in terms that are sufficiently general that it would be difficult for a defendant-manufacturer to show that the standard of care applied by the court in a particular case under state common law is "different from, or in addition to," requirements imposed by the GMPs.[19]

To illustrate the point, suppose that the plaintiff alleges that the head of the defendant-manufacturer's quality assurance (QA) program failed second grade and never returned to school, and that the defendant was negligent in hiring that person. There would be no basis for a court to conclude that liability based on that allegation would require anything "different from, or in addition to," the GMPs' requirements. 21 U.S.C. 360k(a)(1). The GMPs broadly require manufacturers to have QA programs and "sufficient personnel with the necessary education, background, training, and experience to assure that all operations are correctly performed." 21 C.F.R. 820.20, 820.25. Application of those general standards necessarily depends on the circumstances under which a particular device was manufactured. It is exceedingly doubtful, however, that the FDA, in applying that general standard, would consider a second-grade education sufficient for the head of a QA program. By the same token,

[19] Our belief that GMPs ordinarily will not found to preempt state tort claims is based on the "different from, or in addition to," condition for preemption in Section 521(a). We do not dispute that the GMPs impose "requirement[s]" within the meaning of Section 521(a). See 21 U.S.C. 333(f)(1)(B)(i) (referring to Section 360j(f), under which GMPs are promulgated, as imposing "requirements"); 21 U.S.C. 351(h) (same); 21 U.S.C. 360c(c)(2)(B) (same); 21 U.S.C. 360j(f)(2)(C) (same).

the court in a common-law tort suit would not be obligated to conclude, based only on the general standards in the GMPs, that the "different from, or in addition to" condition for preemption of a common-law standard of care had been met. In such a case, involving general federal requirements and general duties under state tort law, the court should invoke the presumption against preemption (see *Hillsborough County* v. *Automated Medical Labs., Inc.*, 471 U.S. 707, 715 (1985)) and conclude that the common-law standard of care, as asserted in the plaintiff's claim, is not preempted.[20]

We note that FDA employees periodically inspect device manufacturers for compliance with the GMPs. See

[20] It does not necessarily follow that a State could, by statute or regulation, adopt a rule requiring all medical-device manufacturers to have their QA programs headed by someone with at least a college degree. It could be argued that such a rule would be preempted by the GMPs, quoted in the text, regarding QA programs and personnel. The generalized nature of those GMPs could reflect a judgment by FDA that personnel qualifications should be assessed on a case-by-case basis. If so, a State would contravene FDA's judgment by adopting a uniform rule. A similar conflict in regulatory approach does not necessarily arise when a properly instructed jury finds that the lack of a college degree rendered a particular employee inadequately educated and, on the basis of that finding, imposes civil liability under general principles of state tort law. A generalized GMP on the same subject contemplates that adequacy will be determined on a case-by-case basis.

To consider a further variation, suppose that the FDA adopted a GMP requiring the heads of medical-device QA programs to have high school diplomas. That GMP would, in the absence of an exemption, preempt both state regulations requiring QA heads to have college degrees and a state common-law standard of care requiring that result in a particular case. Cf. 42 Fed. Reg. 9293 (1977) (FDA regulations prescribing requirements for labeling and conditions of sale of hearing aids preempted state requirements with respect to safety and effectiveness of hearing aids); *id.* at 30,383-30,384; 45 Fed. Reg. 67,329 (1980) (FDA declines to grant exemption for state provisions requiring audiological examinations before sale of hearing aids).

21 C.F.R. 821.50; see also 21 U.S.C. 374. Those employees may determine that a particular manufacturer has violated a GMP. Such a determination of noncompliance (or a formal administrative order to the same effect) would not, of course, bar a tort plaintiff's claim that the same conduct by the same manufacturer also violated state common-law standards that were consistent with the GMPs. Tort liability in those circumstances would not rest on any state-law requirement that was "different from, or in addition to," that required by the GMPs. But cf. *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25, 27-30 (1st Cir. 1995).

Moreover, a determination by an FDA inspector that a particular aspect of a manufacturer's operations *complied* with the GMPs would not be sufficiently formal to bar a private tort action alleging negligence in the same aspect of operations. Even if we assume, *arguendo*, that some individualized determinations by FDA could have such preemptive force (by giving content in a particular context to the general standards in the GMPs), it would, in our view, be only those determinations having the same attributes necessary for an agency decision to have preclusive effect under res judicata principles. See, *e.g.*, *United States* v. *Utah Constr. & Mining Co.*, 384 U.S. 394, 422 (1966). Informal agency determinations that lack at least those attributes are of a different character from statutes and regulations, and it is therefore doubtful that Congress intended them to constitute (or embody) "requirement[s]" within the meaning of Section 521(a).[21] Of course, an FDA rule or order that lacks preemptive force may still inform a court's preemption analysis by

[21] Under 21 U.S.C. 333(f)(2)(A), the FDA may assess civil penalties for serious violations of the GMPs "by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5." Such orders, once final, are presumably entitled to preclusive effect under the doctrine of administrative res judicata.

interpreting the substance of federal statutory or regulatory requirements. See *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984).

IV. The Labeling Provisions Of The Act And Implementing Regulations Do Not Require Summary Judgment For Medtronic On The Lohrs' Failure-To-Warn Claims

The Act authorizes the FDA to adopt requirements for the labeling of devices, but it does not prescribe advertising requirements for the device at issue. See 21 U.S.C. 352.[22] Accordingly, the Lohrs' failure-to-warn claims are not preempted insofar as they allege that warnings should have been made through modes of communication other than labeling. Cf. *Cipollone*, 505 U.S. at 527-529 (plurality opinion) (concluding that state-law failure-to warn claims were not preempted insofar as they concerned channels of communication other than advertising or promotion).

Nor was summary judgment for Medtronic warranted on the failure-to-warn claims insofar as they concern the labeling of the Model 4011. In addressing the labeling of devices, the Act and its regulations for the most part speak in general terms. The Act forbids labeling that "is false or misleading," 21 U.S.C. 352(a), and requires the label to contain certain information, including "adequate directions for use," 21 U.S.C. 352(f). The regulations flesh out the meaning of "adequate directions for use" and other statutory requirements. 21 C.F.R. 801.5; see generally 21 C.F.R. Pt. 801. Neither the Act nor the regulations, however, specifically address whether Med-

[22] The FDA may regulate the advertising of prescription drugs, 21 U.S.C. 352(n), and "restricted" devices, 21 U.S.C. 352(r), 360j(e). See also 21 U.S.C. 331(*l*) (prohibiting representation or suggestion in labeling or advertising that device is approved under 21 U.S.C. 360e or 360j(g)).

tronic was required to disclose on its labels the alleged tendency of its pacemaker lead to fail.

In these circumstances, the federal labeling provisions do not, standing alone, preempt the failure-to-warn claims. The success of those claims depends on a jury determination, under instructions consistent with the federal labeling requirements, that the labeling of Medtronic's device was inadequate. We cannot say that such a determination would of necessity rest on any common-law duty of care that is "different from, or in addition to," (21 U.S.C. 360k(a)(1)) the Act's labeling provisions. It is possible that the FDA, applying the federal labeling provisions, could likewise determine that the labeling of Medtronic's device was inadequate.

The FDA's clearance of Medtronic's pacemaker lead under Section 510(k) as a device substantially equivalent to a pre-Amendments Class III device did not reflect a determination that the labeling of that device was a complete recitation of the device's risks and benefits. This is because the underlying testing needed to produce that information had been deferred under the statutory scheme calling for premarket approval for pre-Amendments Class III devices. Just as 510(k) clearance of a device found to be substantially equivalent to a pre-Amendments Class III device does not constitute a federal determination that the device is properly designed or manufactured, it does not constitute a federal determination that the device is adequately labeled for all purposes.

CONCLUSION

The judgment of the court of appeals should be affirmed insofar as the court held that Section 521(a) does not preempt the defective-design claims advanced by respondents/cross-petitioners and reversed insofar as the court held that Section 521(a) of the Act does preempt the defective-manufacture and failure-to-warn claims advanced by respondents/cross-petitioners, and the case should be remanded to the district court for further proceedings on all of those claims.

Respectfully submitted.

DREW S. DAYS, III
Solicitor General

EDWIN S. KNEEDLER
Deputy Solicitor General

STEPHEN W. PRESTON
Deputy Assistant Attorney General

RICHARD H. SEAMON
Assistant to the Solicitor General

DOUGLAS N. LETTER
MICHAEL S. RAAB
Attorneys

MARCH 1996

☆ U. S. GOVERNMENT PRINTING OFFICE: 1996 405017 40085